

REMARKS

Claims 1-9, 16-18, 28-31, and 35-37 are pending.

The specification has been amended to correct typographical errors appearing in Table 13.

Claims 1, 35, 36, and 37 have been amended by replacing "consisting of" with "comprising." Claim 37 has also been amended to correct a clerical error. The term "comprising" appeared in the claims as originally filed. This amendment addresses and overcomes the outstanding rejection of the claims under 35 U.S.C. §112, first paragraph.

New claims 39-91 have been added. Claims 39-54 correspond to the following originally filed claims:

Originally Filed Claim	New Claim
10	39
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New claims 55-91 claim the same or substantially the same subject matter as the claims of Venkatraman et al., U.S.S.N. 10/850,865, entitled "Transdermal Administration of Fentanyl and Analogs Thereof."

Exemplary support for these claims may be found as follows (references are to Example numbers and paragraphs numbers of the published U.S. application):

New Claim	Exemplary Support
55	0049, claim 22, claim 27, 0048, 0036, 0045
56	Examples 47 & 48
57	0035
58	Examples 47 & 48
59	Examples 47 & 48
60	Examples 47 & 48
61	0045
62	0045
63	0036
64	0036
65	Examples
66	Examples
67	0123
68	Abstract; throughout
69	0031
70	Examples
71	Examples
72	0123
73	Abstract; throughout
74	0047
75	0047
76	0047
77	Examples
78	0049, claim 22, claim 27, 0048, 0036, 0045, Examples 47 & 48
79	0049, claim 22, claim 27, 0048, 0036, 0045, Examples 47 & 48
80	Examples 47 & 48
81	0045
82	0045
83	0036; 0031
84	0123
85	Examples
86	Examples
87	0049, claim 22, claim 27, 0048, 0036, 0045,

New Claim	Exemplary Support
	Examples 47 & 48
88	0049, claim 22, claim 27, 0048, 0036, 0045, Examples 47 & 48
89	0045, 0036, 0051, Examples 47 & 48
90	Examples
91	Examples 47 & 48

Claims 1-9, 16-18, 28-31, and 35-37 stand rejected under 35 U.S.C. §112, second paragraph, on the ground that the phrase “substantially free,” used to describe the undissolved fentanyl, is indefinite. Applicants request that the Examiner reconsider and withdraw the rejection.

It is well-settled that words of degree, such as “substantially free,” do not automatically render a claim invalid. Rather, when words of degree are used, it is necessary to determine whether the patent’s specification provides some standard for measuring that degree. In the present case, undissolved fentanyl manifests itself as dispersed crystals. The specification states that the presence of undissolved fentanyl may be detected by examination with an optical microscope at 20x magnification. Thus, a composition that is “substantially free” of undissolved fentanyl is one in which examination with an optical microscope at 20x magnification yields no discernible evidence of dispersed fentanyl crystals. This is in contrast, for example, to prior art compositions of the type described in Roy et al., “Controlled Transdermal Delivery of Fentanyl: Characterizations of Pressure-Sensitive Adhesives for Matrix Patch Design,” *J. Pharm Sci.* 85(5):491 (1996), where compositions containing over 4% fentanyl were observed to consist of both solution and dispersed fentanyl particles (see P. 494). The claims, therefore, satisfy the requirements of §112, second paragraph, and the rejection should be withdrawn.

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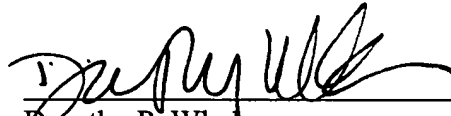
Attorney's Docket No.: 19426-002001

Enclosed is a check in the amount of \$6,380 (\$5,360 for excess claim fees and \$1,020 for the Petition for Extension of Time fee). Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: \_\_\_\_\_

10/11/05



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